

REMARKS

Claims 1, 3-13, 15 and 19 are currently pending in this application, as amended. By this Reply, applicants' have amended claims 1, 4-9, 11, 12 and 15, and have added new claim 19. Claims 2, 14 and 16-18 stand cancelled. No new matter has been introduced into the application by these amendments.

In the action, claims 16-18 which were submitted in the August 26, 2003 Reply, were withdrawn from consideration as not being drawn to the constructively elected invention based upon the claims which were originally submitted and acted upon in the first office action. In response, applicants have cancelled claims 16-18 without prejudice to filing of a divisional application.

In the action, the notation by the examiner of the prior rejections under 35 U.S.C. § 112, 102 and 103 being withdrawn is noted with thanks. The new rejections made in the action are addressed in detail below.

Claims 1, 3-13 and 15 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the examiner objected to the phrase "wherein individual fibers are distributed within the composite so that a majority of the fibers do not contact each other." In response, applicants have cancelled the objectionable language from the claims. Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

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The examiner further noted that upon removal of this matter from the claims that the prior rejections under 35 U.S.C. § 102 and § 103 of record in paper no. 9 would be re-applied. Accordingly, applicants will address those rejections in further detail herein with respect to the amended claims.

The claims previously stood rejected under 35 U.S.C. § 102(b) as anticipated by EP 0 551 574 A1 to Chu et al. Applicants respectfully traverse this rejection in view of the amended claims.

Claim 1 is directed to a composite of polymer or ceramic material for the manufacture of components used in biological implants. The composite includes fibers that do not absorb substantial amount of x-rays located in a polymer or ceramic material and x-ray absorbing reinforcing fibers distributed within the composite throughout the fibers that do not absorb substantial amount of x-rays in a defined manner to provide x-ray visibility control for the biological implant components. Independent claim 9 is specifically directed to a component made from a composite of polymer or ceramic material having x-ray absorbing reinforcing fibers distributed throughout the composite wherein an orientation of the x-ray absorbing reinforcing fibers is tailored to a shape and application of the component in a defined manner to provide x-ray visibility control for the component. The benefit of the present invention is the ability to provide a composition and/or implantable components having x-ray visibility control for the component by having

x-ray absorbing reinforcing fibers distributed throughout the composite. This can be done uniformly over a size of the component (see page 8, last paragraph and specification) or the concentrations can be varied and tailored to the specific shape and/or application of the component depending on segments of an implant where a stronger, weaker or even no x-ray visibility is desired (see page 4, last paragraph).

In contrast, Chu et al. is directed to a bone implant comprising first and second non-metallic layers with a metallic braid located therebetween. One preferred polymer disclosed for their construction is polyaryletherketone (PAEK). However, there is no suggestion or disclosure of providing a composite material for the manufacture of components used in biological implants or such biological implant components in which x-ray absorbing reinforcing fibers are distributed within the composite throughout the fibers that do not absorb substantial amounts of x-rays, as recited in claim 1, or x-ray absorbing fibers distributed throughout the component, as recited in claim 9. Chu is limited to the x-ray absorbing fibers (the metallic braid) located between the two non-metallic layers. It is therefore not distributed within the composite throughout the fibers that do not absorb substantial amount of x-rays in a defined manner to provide x-ray visibility control for the implant. This is a distinct advantage of the present invention in order to allow an implant component to be provided which has stronger, weaker or even no x-ray visibility in a desired or defined area, depending upon the concentration of the

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x-ray absorbing reinforcing fibers and their distribution throughout the remainder of the composite material. To the extent that Chu et al. merely disclose a braided, wound, woven or matted metal fiber layer located between two non-metallic layers in a generally uniform manner as shown in Figure 2, there is no suggestion or disclosure of such tailoring of x-ray visibility. Accordingly, applicants' submit the claims 1 and 9 are patentable over this reference. The remaining claims depend directly or indirectly from claims 1 or 9 and should be similarly patentable for the reasons noted above. Accordingly, withdrawal of the Section 102 rejection of claims 1, 3-13 and 15 are respectfully requested.

The prior action also rejected claims 1-15 under 35 U.S.C. § 103 as unpatentable over the combination of WO 96/19336 to Loher et al. and GB 2203342 A to Ellis. Applicants respectfully traverse this rejection.

Loher et al. discloses a component made of round rods formed of carbon fiber reinforced PAEK. However, there is no suggestion or disclosure of x-ray absorbing reinforcing fibers distributed within the composite throughout the fibers that do not absorb substantial amounts of x-rays in a defined manner to provide x-ray visibility control for the component. The carbon fiber are not x-ray absorbing and, therefore, do not meet the requirements of claims 1 or 9.

Ellis also fails to address the deficiencies of Loher et al. Ellis is directed to the use of a gold or other suitable metallic thread in connection with a surgical soft

tissue implant, such as a vascular prosthesis or prosthesis for replacement of ligaments and tendons. The gold thread is selected so that it will not substantially interfere with the performance of the implant and must remain ductile or otherwise highly flexible. The wire is incorporated in the prosthesis as a single wire or four wires which are woven into the prosthesis during manufacture. There is no suggestion or disclosure of the use of x-rays absorbing fibers distributed within the composite throughout the fibers that do not absorb substantial amount of x-rays in a defined manner to provide x-ray visibility control for the biological implant components, as recited in claim 1, or of x-ray absorbing reinforcing fibers distributed throughout the composite with the x-rays absorbing fibers being tailored to a shape and application of the component in a defined manner to provide x-ray visibility control for the component, as recited in claim 9. Additionally, Ellis clearly teaches that the single gold wire or four wires must be highly flexible or sufficiently ductile so they do not interfere with the performance of the implant. There is no suggestion or disclosure that these wires are reinforcing fibers distributed throughout a composite which can also enhance the strength of the composite. Accordingly, applicants submit that claims 1 and 9 are patentable over this reference. The remaining claims depend directly or indirectly from claims 1 and 9 and should be similarly patentable. Accordingly, withdrawal of the Section 103 rejection of the claims is respectfully requested.

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If the examiner believes that an interview, either telephonically or in person, would help to advance the prosecution of this application, it is respectfully requested that the examiner contact the undersigned at the examiner's convenience.

In view of the foregoing amendment and remarks, applicants respectfully submit that the present application, including claims 1, 3-13, 15 and 19, is in condition for allowances and a notice to that effect is respectfully requested.

Respectfully submitted,

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